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The following information was drawn from documents submitted by the applicant.

A review request in accordance with Para. 44 of the Patents Law has been filed.

54 Body function monitor.

57 The invention relates to a body function monitor with a sensor array with at least a first sensor medium to record physiological measurements, a sensor signal analysis module with a test module for verification as to whether the physiological measurement recorded with the first sensor medium represents a critical or non-critical body state, and a display medium to depict when the physiological measurement represents a critical body state. In doing so, it is intended that the sensor signal analysis module is supplied by at least a second sensor signal that represents a physiological measurement different from the first recorded physiological measurement and that the test module is designed to verify the physiological measurement recorded on the first sensor as to whether it represents a critical or non-critical body state while taking into account at least the second sensor signal

Column 1

Description

This invention relates to a body function monitor with a sensor array with at least a first sensor medium to record physiological measurements, a sensor signal analysis module with a test module to verify whether physiological measurements recorded with the first sensor medium represent a critical or non-critical body state, and a display medium to depict that the physiological measurement represents a critical body state.

Monitoring body functions by means of body function monitors are known per se. For example, at intensive care units (ICU), body functions such as pulse, blood oxygen saturation, body temperature, and so on, must be continually monitored using a plurality of sensors. However, certain body functions are also monitored in healthy individuals to determine health status, for example by using blood pressure measuring devices, pulse measuring instruments, thermometers, and similar. Using some of these devices, the respective body functions can be monitored on a continual or semi-continual basis. For example, this is made possible by commercially available multi-purpose instruments that are worn like a wristwatch and that display measurements such as ambient temperature or atmospheric pressure in addition to blood pressure and pulse.

However, such body function monitors can only be used in a restricted scope if monitoring is continually required to determine whether a user's body is in a critical state or not. In ICUs, this assessment can be left up to an ICU physician. However, this is not possible or sensible when it comes to continuous body function monitors used by healthy individuals, especially to warn of pending illnesses or unhealthy, physical stress. In fact, there are limits for physiological measurements, which when exceeded or not met can be categorized as illness-related deviations. However, these limits vary from person to person and are not consistent. For example, a very fast pulse is completely normal in a fit individual when engaged in athletic activity; however, the same high pulse is not normal if only a short set of stairs was climbed. In this case, one might suspect a pending illness. By comparison, in an unfit individual, an increase in the pulse when climbing stairs is only an indication of general poor physical shape, but not overly worrying.

It would be desirable to design a body function monitor in such a manner that it allows continuous monitoring of body functions without adversely affecting the user's wellbeing in order to provide autonomous warning of a critical body state without requiring medical analysis of the measurements, whereby no danger of frequent erroneous signals or the absence of signals for actual, critical health conditions exist.

This invention [illegible] to develop an innovative concept for commercial applications.

The solution to this task is claimed independently. Preferred embodiments are stated in the sub-claims.

Therefore, in accordance with this invention, a portable body function monitor may be provided with a sensor array with at least a first sensor medium for non-invasive recording of vital body functions, a sensor signal analysis module with a test module to verify whether the physiological measurements recorded with the first sensor medium

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represent a critical or non-critical body state, and a display medium to depict that the physiological measurement represents a critical body state, so that the sensor signal analysis module is supplied at least with a second sensor signal that represents a measurement differing from the physiological measurement recorded by the first sensor medium, and the test module is designed to verify the physiological measurement recorded at the first sensor as representing a critical or non-critical body state under consideration of at least the second sensor signal, whereby especially the short-, medium- and/or long-term time lapses take into account at least one and preferentially each of the first and second signals as well as others if required - preferentially all sensor signals – and whereby preferentially all sensors are accommodated at one location at least to determine the physiological parameters.

By the analysis performed in accordance with this invention of at least one additional sensor signal, a substantially improved test can be conducted of the measurement collected by the first sensor. One thus avoids that a critical condition, such as a pending illness, a massive and [illegible] one-time physically dangerous overload or a condition of shock is indicated only because one single sensor briefly indicates an atypical value. It is important that not just a second sensor identical to the first is provided, or a second sensor set up differently from the first but still determining the same physiological magnitude; instead, an analysis should result that takes into account completely different variables. If the first sensor indicates an inherently critical body state, taking the second parameter into consideration allows one to easily determine whether the alleged critical body state is even plausible and critical if applicable. Simultaneously, an early warning is assured when a plurality of analyzed measurements collectively indicate that a critical deviation exists. As a result of the proposed collective analysis of multiple sensor signals pertaining to various measured parameters, medical intervention to analyze the individual measurements becomes essential and is only required in order to initiate suitable preventive or therapeutic measures for body states identified as critical.

The first sensor medium can be designed for non-invasive, direct or indirect measuring of a physiological parameter from a group consisting of blood pressure, pulse, body temperature, gastric pH, blood oxygen saturation, skin moisture, skin color, the blood's carbon dioxide concentration, and breathing rate. Non-invasive measurement from the outside is hereby preferred because it impacts the body function monitor user's wellbeing only to a minimal degree.

The second sensor signal may be supplied from a sensor on the sensor signal analysis module that is designed to measure a value representing bodily stress. Bodily stress can initially include stress caused solely by external influences. These include those parameters that cause stress and an overall bodily indisposition, such as high ambient noise levels, high pollen counts for allergic individuals, high concentrations of hazardous trace gases such as ozone, nitrogen oxides, carbon monoxide, hydrocarbons, sustained exposure to neon light and so on, which can be distinguished

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with photo-sensors while using suitable spectral filters and taking into consideration natural light intensity that varies with the system frequency over time.

When sustained, these types of factors often increase the susceptibility of stressed individuals to illness. Thus, the test module can be designed in such a manner that critical body states of body function monitor users, who are exposed to noise for example, will be indicated more frequently than normal. In this way, response characteristics are simultaneously adapted to the respective wearer.

However, it should be noted that taking the second sensor signal into consideration can be accomplished by various means, even for one and the same wearer, and that especially the time lapse of the transmission signals is significant for analysis. Thus, an asthmatic should be warned much earlier of an asthma attack if an incipient shortness of breath is recorded with a respiration frequency sensor, such as a pulse oximeter and if simultaneously the ozone concentration, especially at high, also considered ambient temperatures, is very elevated over a longer period of time. This scenario represents a mid-summer, sunny weather phase in which the organism is subject to considerable stress anyway and the asthmatic should be warned early in this case. In contrast, a short-term increase in the ozone concentration, especially with a simultaneous increase in UVB radiation and a decrease in atmospheric pressure could indicate that users of the portable body function monitor have exposed themselves to the invigorating climate of the Alps, so that shortness of breath should not be particularly worrisome.

Instead or in addition to these sensor signals that represent bodily stress due to external influences, those types of sensor signals indicating motion or another bodily stress can also be analyzed. In particular, these include signals from accelerometers, especially 3-D accelerometers. Mounting the sensors on the torso or its vicinity results in improved analyzability, especially for band pass filtering of the sensor signal. These types of sensors allow one to determine from the typical time pattern whether users are climbing stairs, moving quickly as in a sport, or resting. Depending on the wearer's movement state emerging from the typical time pattern, one can then determine whether the pulse increase results from climbing stairs briefly or a rest state, and whether it should thus be categorized as critical or non-critical, e.g. after sustained athletic activity. One can also determine when a movement phase ends and whether the pulse decreases again after the stress within an appropriate period.

This shows in turn that gathering sensor data over time is very sensible for analysis in order to verify the presence of a critical body state. Preferentially therefore, one should not analyze a single sensor value; instead by considering a series of sensor value, one should determine whether the individual measurement represents a plausible and normal progression of the previous sensor signals, indicates a simple measurement error that could be the case particularly in extreme changes and/or extreme absolute values, or indicates a pending change of a critical body state. Preferentially, one should dynamically vary or change the thresholds by which a sensor value is categorized as critical. In doing so, the time of day can be considered in the analysis

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in order to dynamically accommodate standard values.

This invention's body function monitor is not limited to analyzing only one sensor signal while taking into account a second sensor signal. Rather, it is even preferred if a preferably large number of different physiological and non-physiological measurements are jointly analyzed in order to indicate a critical state, since the analysis of a larger number of measurements increases the accuracy with which a critical body state can be predicted. At the same time, a suitable selection of the measured magnitudes can enable one to predict why a certain state is critical.

Preferentially, only non-invasive measurements will be undertaken. Furthermore, optical measurement processes are preferentially implemented for a plurality of physiological measured parameters. To this end, for example, an optical pulse oximeter, preferentially one that operates on a reflection principle, can be used as a sensor due to its more compact construction, into which an opto-transmitter emitting two differing wavelengths as well as a receiver sensitive to one of these wavelengths are designed. A pulse oximeter is especially preferred because the time variation of the intensities inherently indicates the pulse, blood oxygen saturation can be determined from the relation between the intensities of both wavelengths, and respiration frequency can be determined from the time lapse of oxygen saturation. Thus, assuming a sufficient time resolution of the measurements, three different physiological measured quantities can be obtained using a single sensor. An additional preferential optical measurement device analyzes the skin's spectral characteristics to respond to shock-like paleness, sunburn-type redness, and so on.

In addition, certain electrical sensors are preferred. Besides the skin's electrical conductivity, the dielectric properties of zones close to the skin produce good, non-invasive, measurable, and still meaningful physiological values. With capacitor plates arranged in an adjoining manner, a variation in the non-homogenous electrical field allows one to deduce a change in the dielectric properties of the adjoining body parts, which are characteristic for polarization effects associated with nerve stimulation.

It is not absolutely required to identify all sensor signals on the user. Especially those sensor signals that are representative of external stress such as bio-weather can be identified in a centralized manner due to their regionally slight variations and can be transferred to the body function monitor. This transfer can be currently accomplished in real time using radio communications for example or, if only one time-delayed analysis of the physiological measured quantities is desired, by other means, such as through a connection to a PC to which bio-weather data is transferred via the Internet. As an option, the body function monitor can be broken down into a portion carried by the user comprising a data receiving function as well as a data pre-analysis function if required, and a location-specific portion, in which the bio-weather data is stored. It is evident that besides bio-weather values such as trace gases, temperature, humidity, pollen count and so on, other important parameters can be taken into account, such as local incidence of illnesses and so on.

As mentioned, it is especially preferred that the test module is designed for time-independent analysis of the sensor signals. In addition, it can be linked with a memory storage module to store measured sensor signals and/or data derived from them. The test module then performs

Column 5

an analysis of the sensor signals while taking into account the previous signal response and can then also determine whether a particular, current value corresponds to a probable and therefore expected behavior. If not, it may be provided in particular that additional measurements are first recorded prior to indicating a critical body state, especially with higher sampling rates or the recording of additional physiological parameters not continually measured in order to conserve energy. It is preferred that an indication regarding a critical state is first displayed when such initiated additional verification indicates a critical body state, especially on a continuing basis.

The drawings listed below further illustrate this invention.

Fig. 1 depicts a basic representation of a body function monitor being used in accordance with this invention. According to Fig. 1, a body function monitor generally labeled as 1 comprises a number of sensors 3, 4, 5 attached to the body of user 2, as well as sensor 6 to measure external influencing parameters.

Sensor 3 is an optical pulse oximeter that operates on a reflection principle and with which the pulse, blood oxygen saturation and respiration frequency are determined per se by known means.

Sensor 4 is a thermo element with which the skin temperature is measured to represent the body temperature parameter.

Sensor 5 is an accelerometer attached to the torso, which is set up to measure the torso's acceleration in all three spatial axes with three pairs of orthogonally arranged, measuring sub-sensors (not depicted).

Sensor 6 serves to measure ambient temperature.

The output signals of sensors 3 to 6 are supplied by wires to body function monitor 1 where they are each connected to matched amplifier 7. After signal conditioning (not depicted) as required, which may include a band pass filter to suppress high-frequency noise above 15 kHz and lower frequency drift below 2 Hz in the signals originating from the accelerometer, the signals are converted in respective, preferentially dedicated analog/digital converters 8 and connected to test module 9 that is designed to verify the conditioned and digitized signal values for indications of the presence of a critical body state and if such presence exists, it activates indication 10 in the form of a red LED.

Body function monitor 1 is operated as follows.

First, characteristic values are transferred to body function monitor 1, which indicate age, sex, and weight of user 2. Sensor signal patterns are derived from these in body function monitor 1 that indicate a deviation from a non-critical body state.

Then, sensors 3, 4, 5 of the body function monitor are attached. The body function monitor is thereby ready for operation.

If users go out into the open to engage in a sport in the course of a summer day, their skin temperature will increase. Their pulse and respiration frequency will increase also.

While increased skin temperature, high pulse, and fast respiration are typical indications of an illness, test module 9 records intense acceleration that is associated with athletic activity. It therefore concludes that no critical body state exists.

Column 6

Right after the athletic activity, the pulse is still high, the user's respiration is fast, and the body is still heated up. The test module determines that although no intense acceleration is being recorded, these types of acceleration did exist just previously. Again, test module 9 determines that no critical body state exists.

The user's pulse and respiration frequency gradually drop off at the same time. The test module determines through comparison with target values that the reduction is occurring within the expected timeframe after athletic activity and does not send a warning signal.

An increase in body temperature is not considered as critical since the external temperature is high and the user engaged in intense movements.

However, if the user has already received a sunburn, the temperature of such stimulated skin will remain significantly higher than normal. This condition will remain after the pulse and respiration have normalized and the ambient temperature has decreased. Test module 9 now determines that there is no normal pattern with which the increased skin temperature can be explained. As a result, a warning signal is indicated that a critical body state exists.

Although body function monitor 1 is depicted next to user 2 and in comparative size for viewing's sake, the body function monitor according to this invention is designed as an integrated device to be typically worn in practice on the wrist or a belt. A practical embodiment of a lab prototype can comprise a commercially available data-logger by US Robotics weighing less than 300 g for example, to which are attached commercially available accelerometers by Sicovend which are used in the automobile industry for airbags, as well as a commercially available blood pressure measuring device made by A&D Medical.

Instead of providing a dedicated A/D converter for each sensor, the analog signals could also be run through a multiplexer to a single converter on an alternating basis.

It is evident that not only critical body states can be displayed, but also a general performance level or health condition, as well as individual physiological measurements.

It is also evident that the body function monitor can be combined with other devices, such as a GPS system to record and/or map one's location.

Even though it is not explicitly depicted in the embodiment, it is preferred and possible to store all or some of the recorded data, or parameters derived from it, and to later obtain a read-out for external analysis. Thus, statistical analysis can be conducted using data obtained from especially many different body function monitors while taking into account the statistical characteristics of their various wearers.

Even though not explicitly depicted in the embodiment, it is preferred if the body function monitor can be fit to various users. This is made possible by selecting from specific sensors, such as atmospheric toxin measurement sensors for job-related exposure of individuals to such conditions. It is also made possible by adjusting the critically regarded pickup thresholds to the users. This type of adjustment, pertaining to age, body size, weight, sex, and medical history, can be made when placing the device into operation and/or

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they can take place adaptively once in operation. In such a case, the body function monitor can be designed to store and retrieve various user profiles. The adjustment may also take place in an adaptive manner, for example whereby after receiving a warning signal, the user enters in that no critical body state exists.

The body function monitor can be used especially for rehabilitation, strength training for infarct patients, self- or remotely-monitored outpatients and or older individuals, as well as athletes in performance training.

Claims

1. Body function monitor with a sensor array with at least a first sensor medium to record physiological measurements, a sensor signal analysis module with a test module to verify whether the physiological measurement recorded by the first sensor medium represent a critical or non-critical body state and
a display medium to depict that the physiological measurement represents a critical body state, **characterized in that**
the sensor signal analysis module is supplied by at least a second sensor signal that represents a measurement differing from the measurement recorded by the first sensor medium and
the test module is designed to verify whether the physiological measurement recorded by the first sensor medium is a critical or non-critical body state while taking into account at least the second sensor signal.

2. Body function monitor according to the preceding claim, wherein the first sensor medium is designed to directly or indirectly measure a physiological value from a group consisting of blood pressure, pulse, body temperature, gastric pH, blood oxygen saturation, skin moisture, skin color, the blood's carbon dioxide content, and respiration frequency.

3. Body function monitor according to one of the preceding claims, wherein the second sensor signal is sent from one sensor to the sensor signal analysis module that is designed to measure values representing bodily stress.

4. Body function monitor according to the preceding claim, wherein the second sensor signal is derived from a sensor suitable to measure ambient temperature, atmospheric pressure, light intensity, especially artificial light, natural light and/or UVB radiation, acoustic pressure, plant pollen counts and/or one or several atmospheric trace gases, especially ozone, nitrogen monoxide, nitrogen dioxide, and/or hydrocarbons, especially solvents appearing in polluted workplaces, and/or a sensor designed as an accelerometer, especially a 3-D accelerometer.

5. Body function monitor according to the preceding claim, with an accelerometer as a sensor to generate the second sensor signal, wherein the accelerometer is designed to be attached to the wearer's body, especially on the torso or its vicinity, and/or wherein the bandwidth of the sensor signal processed at the sensor signal analysis module and/or

Column 8

by the test module is limited to a range of 2 Hz to 20 kHz, preferentially 2 Hz to below 15 kHz.

6. Body function monitor according to one of the preceding claims, wherein the second sensor signal is derived from a sensor suited to measure an additional physiological value, especially from the aforementioned group.

7. Body function monitor according to the preceding claim, wherein at least one of the sensor signals is derived from a sensor suited to measure pulse oximetric data, especially to measure oxygen and/or carbon dioxide contents in the blood.

8. Body function monitor according to the preceding claim, wherein the pulse oximeter is designed as a reflective pulse oximeter.

9. Body function monitor according to one of the preceding claims, which also comprises a data receiver that is suited to receive signals of a remote sensor or one separate from the wearer and that stores received data as the second sensor signal to the sensor signal analysis module.

10. Body function monitor, wherein the display is designed as an indicator that can be read by the wearer or as an acoustic signal transmitter.

11. Body function monitor according to one of the preceding claims, wherein a plurality of sensor signals representing physiological measurements and/or a plurality of sensor signals representing bodily stress are supplied to the sensor signal analysis module.

12. Body function monitor according to one of the preceding claims, wherein the test module is designed for time-dependent analysis of the sensor signal.

13. Body function monitor according to one of the preceding claims, wherein a memory module is provided to store measured sensor signals and/or data derived from these.

14. Body function monitor according to one of the preceding claims, wherein the test module is designed to verify the existence of a critical body state while taking into account the data stored in the memory module.

15. Body function monitor according to one of the preceding claims, wherein the test module is designed to indicate a critical body state only when a critical body state was identified for a particular period in a sustained or predominant manner.

16. Body function monitor according to one of the preceding claims, wherein the test module is designed to derive the probability of the existence of a critical body state from a plurality of individual sensor signals, and to identify the existence of a critical body state only when several individual probabilities collectively point to a critical body state.

One (1) page of drawings is attached hereto.

Drawing page 1

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Fig. 1